Selectra Accessory Kit and Selectra Slitter Tool Modifications

Special 510(k) Premarket Notification

1. 510(K) SUMMARY

Date Prepared: August 22, 2013

Name and Address of Sponsor:
BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035

AUG 2 3 2013

Establishment Registration Number: 1028232

510(k) Contact Person and Phone Number:
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Device Name:

Proprietary Name:	Selectra Accessory Kit, Selectra Slitter Tool
Common Name:	Catheter Guide wire
Classification:	Class II (21 CFR 870.1330)
Product Code:	DQX, DQY

Predicate Devices:

- Selectra Accessory Kit (K111839, dated September 26, 2011)
- Selectra Slitter Tool (K112482, dated September 26, 2011)

Indications for Use:

The Selectra Accessory Kit/Selectra Slitter Tool is used in conjunction with the Selectra CS lead introducer system to facilitate lead implantation in the left side of the heart via the coronary sinus.

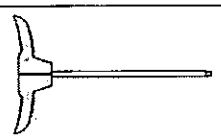
Device Modifications:

The legally marketed Selectra Accessory Kit and Selectra Slitter Tool are accessories to the Selectra lead introducer system, which is specifically used for the placement of coronary sinus leads. The modifications made to the legally marketed devices include a newly designed TVI tool, shelf life extension for the Selectra Accessory Kit/Selectra Slitter Tool, and new sterile packaging for the Selectra Slitter Tool.

Technological Characteristics and Substantial Equivalence:

The substantial equivalence claim between the subject and the predicate device is supported by the information included in the premarket notification. This includes the following information:

- Description of the subject and predicate devices
- Intended use of the subject and predicate devices
- Performance of the subject and predicate devices
- Technological characteristics of the subject and predicate devices
- Validation Testing

Table 1: Substantial Equivalence of the Modified Selectra Accessory Kit and Selectra Slitter Tool		
Technical Data	**Selectra Accessory Kit (Predicate)**	**Selectra Accessory Kit (Proposed)**
Configuration	1 Accessory Kit Including: - 1 Guide Wire - 4 Transvalvular Insertion (TVI) Tools - 1 Selectra Slitter Tool - 1 Torquer - 2 Check-valves - 2 Stop-cocks - 2 Sealing Caps - 1 Syringe - Technical Manual	1 Accessory Kit Including: - 1 Guide Wire - 4 Transvalvular Insertion (TVI) Tools (subject of this Special 510(k)) - 1 Selectra Slitter Tool - 1 Torquer - 2 Check-valves - 2 Stop-cocks - 2 Sealing Caps - 1 Syringe - Technical Manual
TVI Tool Design Dimensions Materials Manufacturer	 Outer Diameter: 5 F Inner Diameter: 3 F PTFE, PP Galt Medical Corp.	 Outer diameter: 4.8 F Inner diameter: 1.26 F PEBAX 7233 BIOTRONIK SE & Co. KG
Product Packaging	The products are packaged in a sterile blister within a sterile pouch. The blister and pouch are placed in an outer cardboard box with label and a quality seal.	
EtO Sterilization	EtO sterilization for single use only. The sterilization process is validated at least bi-annually.	
Shelf Life	6 months	2 years
Technical Data	**Selectra Slitter Tool (Predicate)**	**Selectra Slitter Tool (Proposed)**
Selectra Slitter Tool Design Compatibility Materials Manufacturer	 Can be used with all coronary sinus leads with a diameter of 4.6F to 5.8 F. Body Material – Acrylonitrile Butadiene Blade Material – Stainless Steel Creganna	

Product Packaging	The products are packaged in a sterile blister within a sterile pouch. The blister and pouch are placed in an outer cardboard box with label and a quality seal.	The products are packaged in two sterile pouches. Both pouches are placed in an outer cardboard box with label and a quality seal.
EtO Sterilization	EtO sterilization for single use only. Sterilization process is validated at least bi-annually.	
Shelf Life	6 months	2 years

Summary of Non-Clinical Testing:

The substantial equivalence claim between the subject and the predicate devices is supported by the information included in this premarket notification. This includes the following:

- Comparison of the attributes and specifications of the subject and predicate devices
- Subject device risk analysis
- Subject device validation testing which includes the following testing:

New TVI Tool:

- Cytotoxicity
- Sensitization – Local Lymph Node Assay (LLNA)
- Irritation or Intracutaneous Reactivity
- Acute Systemic Toxicity in the Mouse with 4 Extracts
- Material Mediated Pyrogenicity - Rabbit Pyrogen Test
- Hemocompatibility Evaluation
- Compendium of Biological Evaluation
- EtO Residual Gas Analysis
- Environmental Preconditioning
- Release of Particulate Matter
- Tests After Environmental Preconditioning and Shelf Life (25 months)
- Labeling on Sales / Sterile Package - Accompanying Documentation

Extended Shelf-Life for the Selectra Accessory Kit and Selectra Slitter Tool:

- Determination of Shelf Life (25 months) – Transport Test, Drop Test, Completeness of Unit
- Inspection of Seldinger Guide Wire
- Inspection of Syringe
- Inspection of Check Valve, Stop-Cock, and Sealing Caps
- Inspection of TVI and slitter tool
- Proof of Sterilization after Accelerated Aging of 25 Months

New Sterile Packaging for the Selectra Slitter Tool:

- Labelling on Sales / Sterile Package - Accompanying Documentation
- Environmental Preconditioning
- Determination of Shelf Life (25 months) and Integrity of Sterile Packaging
- EtO Sterilization Cycle Product Adoption
- Tests after Environmental Preconditioning and Accelerated Aging (25 Months)

Conclusion:

BIOTRONIK considers the modifications to the Selectra Accessory Kit and Selectra Slitter Tool to be substantially equivalent to the legally marketed predicate devices through the data and information presented. No safety or effectiveness issues were identified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 23, 2013

Biotronik, Inc.
Mr. Jon Brumbaugh
Vice President, Regulatory Affairs and Compliance
6024 Jean Road
Lake Oswego, OR 97035 US

Re: K131978
Trade/Device Name: Selectra Accessory Kit, Selectra Slitter Tool
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX, DQY
Dated: July 24, 2013
Received: July 25, 2013

Dear Mr. Brumbaugh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131978

Device Name: Selectra Accessory Kit and Selectra Slitter Tool
Indications for Use:

The Selectra Accessory Kit / Selectra Slitter Tool is used in conjunction with the Selectra CS lead introducer system to facilitate lead implantation in the left side of the heart via the coronary sinus.

Prescription Use ___✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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